

**HL7 SPL Working Group Process Communication Forum Telecon  
Wednesday, Mar 24, 2010**

Check out the SPL Working Group WIKI @:  
<http://spl-work-group.wikispaces.com>

**Questions on SPL:**

ER/DL regulatory questions? Send to [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)

SPL technical questions? Send to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov)

**Meeting Minutes:**

Follow up questions about SPL indexing

- Concern whether the indexing term for an indication would need to match the content of labeling text; concern whether content of labeling text would need to match one or more indication indexing terms.
- For questions or proposed corrections to the FDA established pharmacologic class term table, e-mail to [SEALD@fda.hhs.gov](mailto:SEALD@fda.hhs.gov) with specifics.

Link to Products required to have Medication Guides:

<http://www.fda.gov/Drugs/DrugSafety/UCM085729>

Link to notice for Proposed Rule: *Electronic Distribution of Content of Labeling for Human Prescription Drug and Biological Products*: <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=200910&RIN=0910-AG18>

Link to Pharmacologic Class material at FDA:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162549.htm>

2003 Final Rule: <http://www.fda.gov/OHRMS/DOCKETS/98fr/03-30641.htm>

Content of Labeling [Definition from 2003 Final Rule]: the contents of the package insert or professional labeling, including all text, tables, and figures.

Patient Labeling

The agency's regulation of PPIs is unrelated to the requirement to submit the content of labeling electronically. This rule requires that the content of labeling ... be submitted electronically. It does not alter the current regulatory treatment of PPIs. The PPIs can be submitted in paper or electronic format

under part 11. If the PPI is submitted electronically, it must appear in the electronic format as it would in printed form.

Question about a mapping of SNOMED to ICD-9, SNOMED to MEDRA –

Additional information: public-private partnership for Observation Medical Outcomes Partnership [<http://omop.fnih.org>] has done a massive mapping of SNOMED to MEDRA, and others.

### HL7 Project Scope Proposal for Device modifications to SPL R4 (SPL R5)

If you want to join the Devices subteam, contact Myron Finseth (at [myron.finseth@medtronic.com](mailto:myron.finseth@medtronic.com))

Device subteam meeting is being planned for April. If you are interested in joining the Device subteam and/or attending this meeting, please contact [Myron.finseth@medtronic.com](mailto:Myron.finseth@medtronic.com)

R5 will be backwards-compatible with the current version (R4).

If company doesn't have any medical devices, there will no need to immediately move to R5.

CDRH FURL system – will we continue to use this system? A: we don't really know.

Current focus is on the UDID model.

### Requirement for SPL posting to DailyMed

Various text in approval letters: please post content of labeling within 10 days to company website; please list within 14 days to DailyMed

DIA's FDA day – questions raised about the use of the 'AccessData' location  
(<http://www.accessdata.fda.gov/spl/data/rootid/rootid.xml>)

- One reviewer – reiterated that the FDA didn't want to receive SPL twice
- At least one approval letter has included text asking for the link w/in the 14 days.

Sponsors were asking for clarity on whether FDA prefers the link or actual files, had questions about where the link should/could be placed. FDA did not provide recommendation at this time.

Ginny Ventura (FDA) is working with eCTD activities – she might be a good contact.